WHAT IS CLAIMED IS:

1. A process of treating oral leukoplakia lesions of humans in need of such treatment, the process comprising the step of applying topically to the leukoplakia lesion an effective amount of a clear aqueous formulation comprising:

water;

a water miscible pharmaceutically acceptable polyol;

a pharmaceutically acceptable unsaturated fatty acid ester;

a pharmaceutically acceptable surfactant, and

β-carotene, said β-carotene being in a micellized form within said formulation.

2. A process in accordance with Claim 1 wherein the formulation additionally comprises a pharmaceutically acceptable anti-oxidant.

3. A process in accordance with Claim 2 wherein the pharmaceutically acceptable anti-oxidant is d-alpha-tocopherol or a pharmaceutically acceptable derivative of d-alpha tocopherol having vitamin E activity.

4. A process in accordance with Claim 1 wherein the formulation additionally comprises a compound having vitamin A activity.

5. A process in accordance with Claim 1 wherein the surfactant is polyethoxylated castor oil.

6. A process in accordance with Claim 1 wherein the polyol is glycerol.

7. A process in accordance with Claim 1 wherein the unsaturated fatty acid ester is ethyl linoleate.

8. A process in accordance with Claim 1 wherein the formulation is a gel.

9. A process in accordance with Claim 8 comprising the steps of applying the gel to the leukoplakia lesion at least twice a day.

10. A process in accordance with Claim 1 wherein the formulation comprises:

10 to 50 % by weight water;

5 to 40 % by weight of the water miscible pharmaceutically acceptable polyol;

1 to 20 % by weight of the pharmaceutically acceptable unsaturated fatty acid ester;

10 to 60 % by weight of the pharmaceutically acceptable surfactant, and

0.03 to 9.0 % by weight of β-carotene.

11. A process in accordance with Claim 10 wherein the water miscible pharmaceutically acceptable polyol is glycerol;

the pharmaceutically acceptable unsaturated fatty acid ester is ethyl linoleate, and

the pharmaceutically acceptable surfactant is polyethoxylated castor oil.

12. A process in accordance with Claim 1 wherein the formulation comprises:

20 to 40 % by weight water;

10 to 30 % by weight of the water miscible pharmaceutically acceptable polyol;

1 to 15 % by weight of the pharmaceutically acceptable unsaturated fatty acid ester;

20 to 40 % by weight of the pharmaceutically acceptable surfactant, and

0.3 to 3.0 % by weight of β-carotene.

13. A process in accordance with Claim 12 wherein the water miscible pharmaceutically acceptable polyol is glycerol;

the pharmaceutically acceptable unsaturated fatty acid ester is ethyl linoleate, and

the pharmaceutically acceptable surfactant is polyethoxylated castor oil.

14. A process in accordance with Claim 13 wherein the formulation additionally comprises d-alpha-tocopherol and a compound having vitamin A

activity.

15. A process in accordance with Claim 14 wherein the formulation is a gel.

16. A process in accordance with Claim 15 comprising the steps of applying the gel to the leukoplakia lesion at least twice a day.

17. A process in accordance with Claim 1 wherein the formulation comprises:

50 to 95 % by weight water;

1 to 10 % by weight of the water miscible pharmaceutically acceptable polyol;

0.01 to 2 % by weight of the pharmaceutically acceptable unsaturated fatty acid ester;

0.01 to 5 % by weight of the pharmaceutically acceptable surfactant, and

0.003 to 1.2 % by weight of β-carotene,

1 to 10 % by weight of a pharmaceutically acceptable sweetener;

0.01 to 2% of a pharmaceutically acceptable antibacterial agent;

d -alpha tocopherol or a pharmaceutically acceptable derivative of d-alpha tocopherol having vitamin E activity;

vitamin A palmitate or a pharmaceutically acceptable derivative of vitamin A palmitate having vitamin A activity;

a pharmaceutically acceptable chelating agent;

a pharmaceutically acceptable antifoaming agent;

a flavoring agent, and

a preservative.

18. A process in accordance with Claim 17 wherein the water miscible pharmaceutically acceptable polyol is glycerol;

the pharmaceutically acceptable unsaturated fatty acid ester is ethyl linoleate;

the pharmaceutically acceptable surfactant is polyethoxylated castor oil;

the pharmaceutically acceptable sweetener is xylitol;

the pharmaceutically acceptable antibacterial agent is cetyl pyridinium chloride;

the pharmaceutically acceptable chelating agent is disodium EDTA, and

the preservative is sodium benzoate.

19. A process in accordance with Claim 18 wherein the formulation is an oral rinse.

20. A process in accordance with Claim 19 wherein the formulation comprises:

75 to 95 % by weight water;

2 to 7 % by weight of glycerol;

0.01 to 0.5 % by weight ethyl linoleate;

0.01 to 1 % by weight polyethoxylated castor oil;

0.003 to 10.6 % by weight of β-carotene,

2 to 7 % by weight of xylitol;

0.01 to 1 % of cetyl pyridinium chloride;

0.005 to 0.05 % by weight of disodium EDTA;

0.2 to 1.5 % by weight of flavoring agent, and

0.01 to 0.5 % by weight of sodium benzoate.

21. A clear aqueous composition for topical application in the oral cavity of humans, the composition comprising:

water;

a water miscible pharmaceutically acceptable polyol;

a pharmaceutically acceptable unsaturated fatty acid ester;

a pharmaceutically acceptable surfactant, and

β-carotene, said β-carotene being in a micellized form within said composition.

22. A composition in accordance with Claim 21 wherein the composition additionally comprises a pharmaceutically acceptable anti-oxidant.

23. A composition in accordance with Claim 22 wherein the pharmaceutically acceptable anti-oxidant is d-alpha-tocopherol or a pharmaceutically acceptable derivative of d-alpha tocopherol having vitamin E activity.

24. A composition in accordance with Claim 21 wherein the composition additionally comprises a compound having vitamin A activity.

25. A composition in accordance with Claim 21 wherein the surfactant is polyethoxylated castor oil.

26. A composition in accordance with Claim 21 wherein the polyol is glycerol.

27. A composition in accordance with Claim 21 wherein the unsaturated fatty acid ester is ethyl linoleate.

28. A composition in accordance with Claim 21 wherein the composition is a gel.

29. A composition in accordance with Claim 21 wherein the composition comprises:

10 to 50 % by weight water;

5 to 40 % by weight of the water miscible pharmaceutically acceptable polyol;

1 to 20 % by weight of the pharmaceutically acceptable unsaturated fatty acid ester;

10 to 60 % by weight of the pharmaceutically acceptable surfactant, and

0.03 to 9.0 % by weight of β-carotene.

30. A composition in accordance with Claim 29 wherein the water miscible pharmaceutically acceptable polyol is glycerol;

the pharmaceutically acceptable unsaturated fatty acid ester is ethyl linoleate, and

the pharmaceutically acceptable surfactant is polyethoxylated castor oil.

31. A composition in accordance with Claim 21 wherein the composition comprises:

20 to 40 % by weight water;

10 to 30 % by weight of the water miscible pharmaceutically acceptable polyol;

1 to 15 % by weight of the pharmaceutically acceptable unsaturated fatty acid ester;

20 to 40 % by weight of the pharmaceutically acceptable surfactant, and

0.3 to 3.0 % by weight of β-carotene.

32. A composition in accordance with Claim 31 wherein the water miscible pharmaceutically acceptable polyol is glycerol;

the pharmaceutically acceptable unsaturated fatty acid ester is ethyl linoleate, and

the pharmaceutically acceptable surfactant is polyethoxylated castor oil.

33. A composition in accordance with Claim 32 wherein the composition additionally comprises d-alpha-tocopherol and a compound having vitamin A activity.

34. A composition in accordance with Claim 33 wherein the composition is a gel.

35. A composition in accordance with Claim 21 wherein the composition comprises:

50 to 95 % by weight water;

1 to 10 % by weight of the water miscible pharmaceutically acceptable polyol;

0.01 to 2 % by weight of the pharmaceutically acceptable unsaturated fatty acid ester;

0.01 to 5 % by weight of the pharmaceutically acceptable surfactant, and

0.003 to 1.2 % by weight of β-carotene,

1 to 10 % by weight of a pharmaceutically acceptable sweetener;

0.01 to 2% of a pharmaceutically acceptable antibacterial agent;

d -alpha tocopherol or a pharmaceutically acceptable derivative of d-alpha tocopherol having vitamin E activity;

vitamin A palmitate or a pharmaceutically acceptable derivative of vitamin A palmitate having vitamin A activity;

a pharmaceutically acceptable chelating agent;

a pharmaceutically acceptable antifoaming agent;

a flavoring agent, and

a preservative.

36. A composition in accordance with Claim 35 wherein the water miscible pharmaceutically acceptable polyol is glycerol;

the pharmaceutically acceptable unsaturated fatty acid ester is ethyl linoleate;

the pharmaceutically acceptable surfactant is polyethoxylated castor oil;

the pharmaceutically acceptable sweetener is xylitol;

the pharmaceutically acceptable antibacterial agent is cetyl pyridinium chloride;

the pharmaceutically acceptable chelating agent is disodium EDTA,

and

the preservative is sodium benzoate.

37. A composition in accordance with Claim 36 wherein the composition is an oral rinse.

38. A composition in accordance with Claim 37 wherein the composition comprises:

75 to 95 % by weight water;

2 to 7 % by weight of glycerol;

0.01 to 0.5 % by weight ethyl linoleate;

0.01 to 1 % by weight polyethoxylated castor oil;

0.003 to 10.6 % by weight of β-carotene,

2 to 7 % by weight of xylitol;

0.01 to 1 % of cetyl pyridinium chloride;

0.005 to 0.05 % by weight of disodium EDTA;

0.2 to 1.5 % by weight of flavoring agent, and

0.01 to 0.5 % by weight of sodium benzoate.

39. A clear aqueous gel composition for topical application in the oral cavity of humans, the composition having been prepared by a process comprising the steps of:

admixing a suspension of β-carotene in edible oil with polyethoxylated

castor oil and heating said admixture to approximately 160 to 180 °C and agitating said admixture in said temperature range of 160 to 180 °C until a clear homogeneous solution is obtained;

thereafter cooling said admixture to approximately 130 to 135 °C and adding d-alpha-tocopherol, glycerol and ethyl linoleate to said admixture, the d-alpha-tocopherol, glycerol and ethyl linoleate being added to the admixture at such a rate of addition that the temperature of the resulting mixture is cooled to approximately 85 to 95 ° C;

maintaining the resulting mixture under agitation at 85 to 95° C until a clear homogeneous mixture is obtained;

thereafter adding under agitation water of approximately 55 to 60°C temperature and cooling the mixture under agitation until a clear homogenous product is obtained.

40. A clear aqueous gel composition in accordance with Claim 39 comprising:

20 to 40 % by weight water;

10 to 30 % by weight of glycerol;

1 to 15 % by weight of ethyl linoleate;

20 to 40 % by weight of polyethoxylated castor oil;

0.3 to 3.0 % by weight of β-carotene.